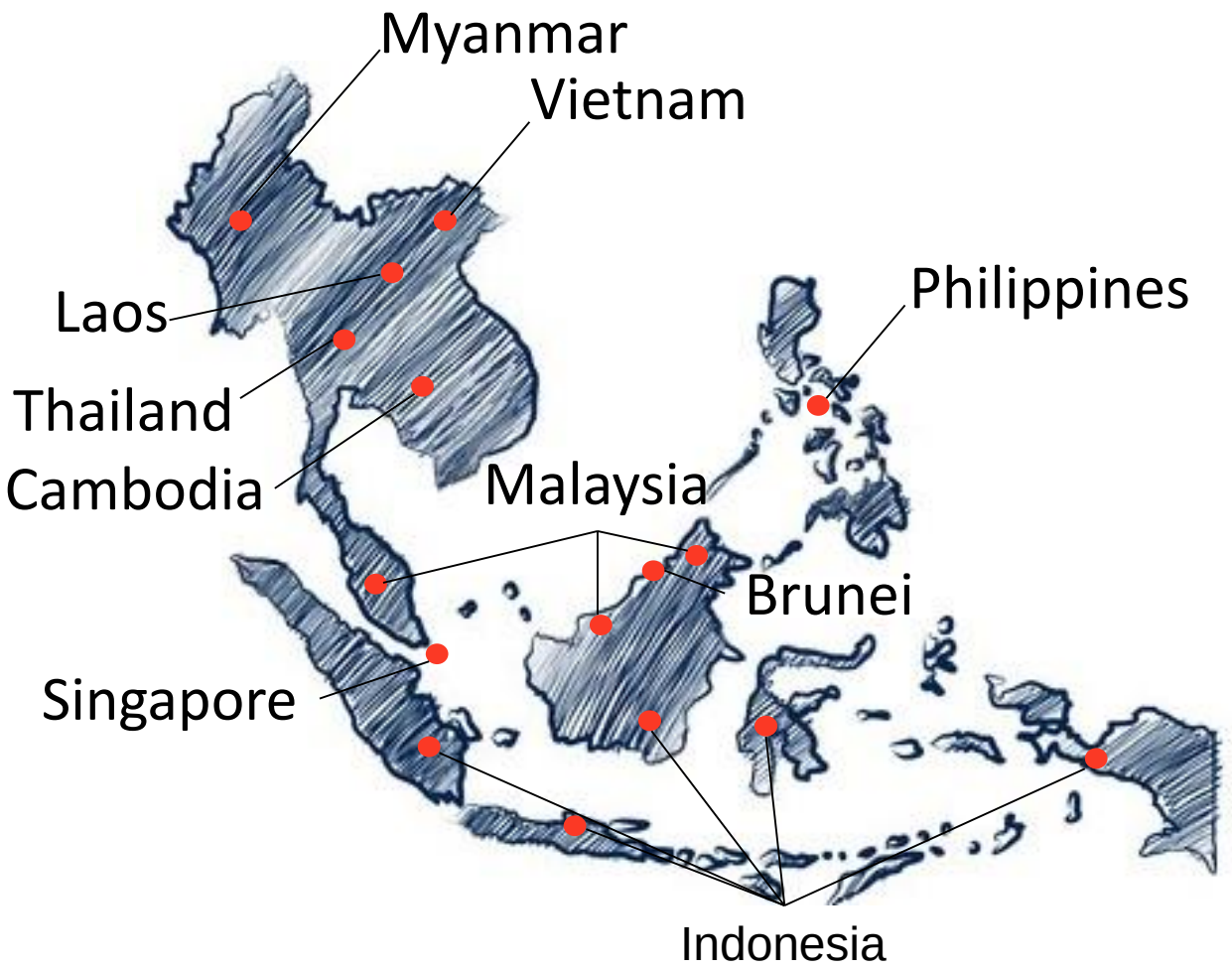
THE ASEAN Medical Device Directive

A WORK IN PROGRESS

Presentation at the AHWP Nov 2016

ASEAN Map

Background & History

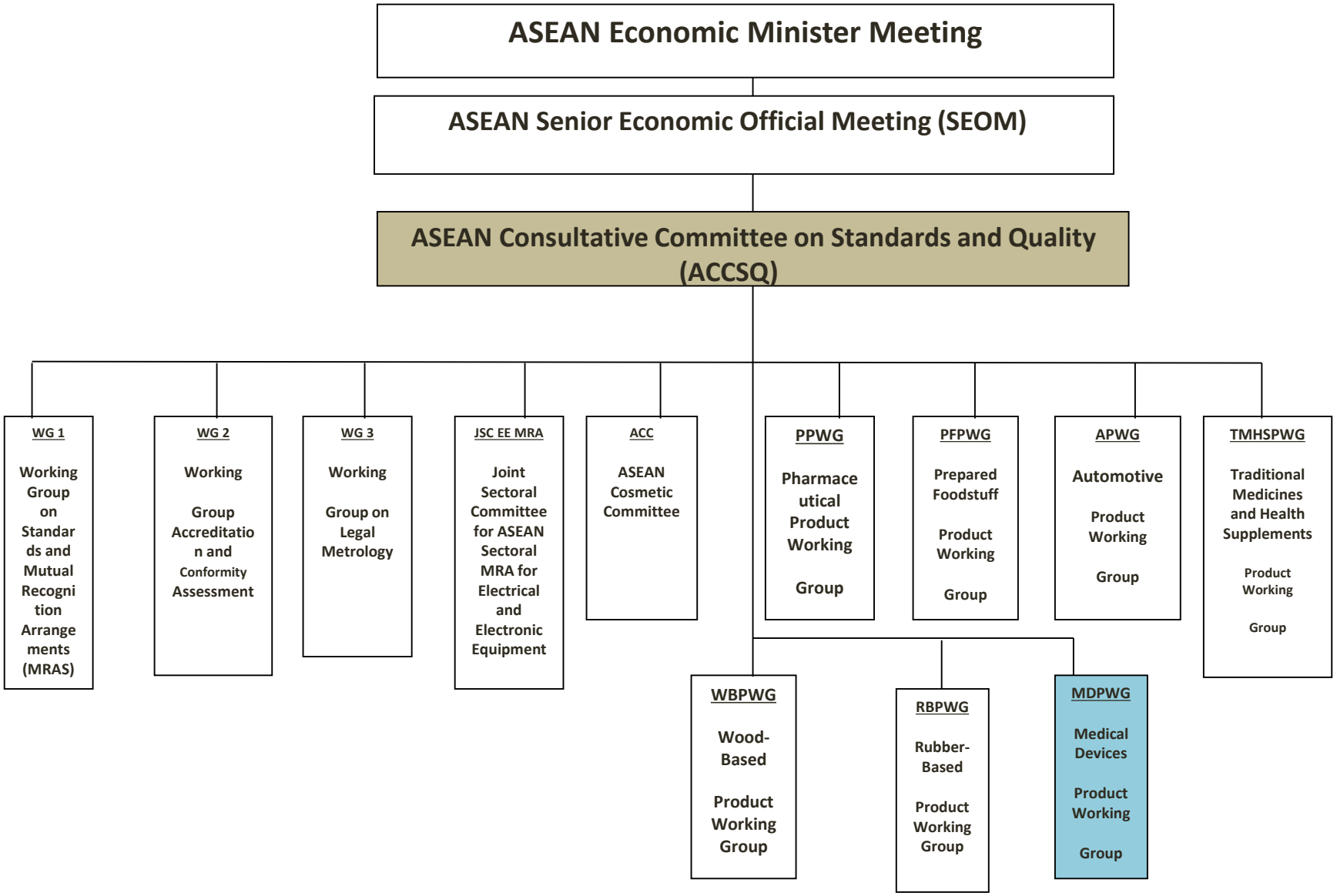


Background of AMDD

2007

- 12th ASEAN Summit-Establish AEC by 2015
- **AEC will establish ASEAN as a single market and production base.**
- An ASEAN single market and production base shall comprise five core elements:
  i. **free flow of goods;**
  ii. free flow of services;
  iii. free flow of investment;
  iv. freer flow of capital; and
  v. free flow of skilled labour

THE ACCSQ Structure



ACCSQ- MDPWG AGENDA

HARMONISED REGULATORY FRAMEWORK: THE ASEAN MEDICAL DEVICE DIRECTIVE

HARMONISED PREMARKET SUBMISSION FORMAT: ADOPTION OF THE COMMON SUBMISSION DOSSIER TEMPLATE

HARMONISATION

HARMONISED SET OF VOLUNTARY STANDARDS IN ASEAN: BASED ON IEC AND ISO STANDARDS

SHARING OF : POST MARKET SAFETY INFORMATION AMONG ASEAN MEMBER STATES

AMDD Guiding Principles

- The primary goal is to protect public health and safety
- The level of regulatory control should be proportional to the degree of risk
- Expedites timely availability and access to safe and beneficial medical devices and to prevent unsafe and ineffective medical devices from entering the market
- Elements of control from design, manufacture and placement in the market shall be put in place to ensure continued safety and quality
- In-line with global harmonization effort to minimize regulatory barriers, facilitate international trade, improve access to new technologies and to reduce the cost of implementing regulation

Milestone of AMDD

01.2007
- AMDD begun in relation to the establishment of AEC

05.2012
- Development of AMDD:
  - National Consultation
  - National Consultation Feedback Review
  - Incorporation of Amendments
  - Legal scrubbing by Member State
  - Legal scrubbing by ASEAN Secretariat's Legal Department
  - **Finalisation of AMDD (Version 15)**

10.2013
- Endorsement by ACCSQ
- Endorsement by SEOM

08.2014
- Signing of AMDD at AEM

01.2015
- AMDD becomes **effective** when ASEAN Member States deposit instruments of ratification with ASEAN Secretariat General

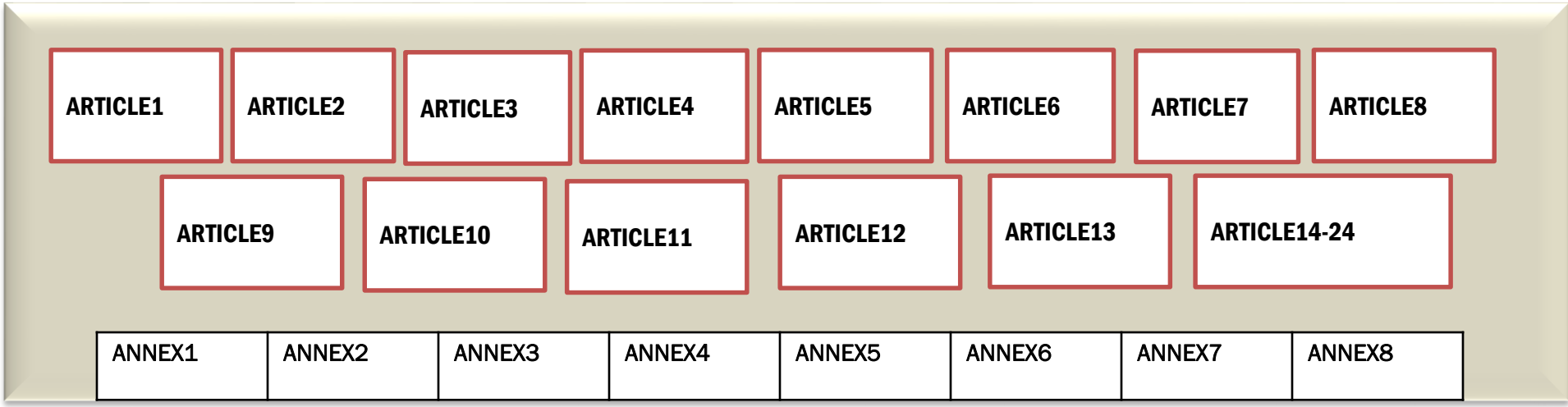
What the AMDD is:

- Defines a basic set of technical requirements to be harmonized within ASEAN.
- Requires Member States to put in place appropriate systems for the registration of medical devices and licensing of dealers who placed these devices on their market.
- Developed in accordance to internationally recognized guidelines, and based on Singapore's regulatory controls.

What the AMDD is NOT:

- **Not intended** to confer **mutual recognition**, - each member state retains sovereign right for registration decisions.
- **Not intended** to **limit MD regulatory controls** to those listed in AMDD. Member states can still implement own country-centric controls.
- **Not aim** to harmonize all elements of MD regulatory control.

AMDD STRUCTURE



Transpose AMDD into National Laws

National Laws of Member States for Medical Device Control

Scope of the ASEAN Regulatory Framework and Controls

- Design & development
- Manufacture, import/ export
- Packaging, labeling, storage

AMDD Covers
Article 3: EPSP
Article 4: Classification of Medical Devices
Article 5 : Conformity Assessment
Article 6 : Registration and placement on the Market
Article 7 : Licensing of Person Responsible for placing medical devices on the markets of member states
Article 8 : Technical Documents for medical devices
Article 9: Reference to Technical Standard
Article 13: Clinical Investigation

- Distribution
- Supply
- Advertising

- AMDD covers
- Article 10 : Labelling
- Article 11 Medical Device Claims

- Surveillance & vigilance
- Installation, T&C, maintenance, calibration, repairs
- Operation, usage
- Decontamination, decommissioning

- AMDD covers

- Article 12 : Post market Alert System

AMDD ARTICLES	AMDD PROVISION	ANNEX
ARTICLE 22	ENTRY INTO FORCE	◉ This Agreement shall be subject to ratification and/or acceptance by Member States in accordance with their internal domestic requirements. ◉ This Agreement shall enter into force on 1 January 2015 and shall be in force only among the Member States that have ratified and/or accepted it.
ARTICLE 23	ANNEXES	The Annexes to this Agreement constitute an integral part of this Agreement.
ARTICLE 24	DEPOSITARY	This Agreement shall be deposited with the Secretary- General of ASEAN, who shall promptly furnish each Member State a certified copy thereof.

ONCE the AMDD is signed..

Moving Forward

- AMDD **does not enter into force** until **instruments of ratification** are deposited with ASEAN Secretary-General.
  - No deadline for deposition but member states have agreed in principle to begin transposing regulatory controls to national legislation.
- Administrative elements of AMDD would begin to be managed by **ASEAN Medical Device Committee (AMDC)**,
- From time to time, where necessary, there will be **amendments** to technical requirements to ensure AMDD is continuously **aligned** to **international best practices**
- Further areas of harmonization would be looked at e.g. definition for IVD?.

Basic Steps to Compliance

- A Common Submission Dossier
  - Executive Summary
  - Risk Assessment
  - EPSP
- Same Definition
- Common Classification rules
- Agreed Standards
- Acceptable Conformity Assessment
- Participation in post market vigilance and surveillance among member states

What are requirements of AMDD?

- Establishment Licence
- Product registration
- Device classification
- CSDT
  - Executive Summary
  - Quality Management System
  - Technical File
  - Post Market Requirements
  - Declaration of Conformity

CONFORMITY ASSESSMENT SYSTEM OF AMDD FOR PRODUCT REGISTRATION

Elements of CA

- QMS (ISO 13485 or equivalent)
- Post-market surveillance system (GHTF recommendations)
- Summary technical documentation (ASEAN CSDT)
- Declaration of conformity (DoC) (GHTF recommendations)

Quality Mgmt System (QMS)

- For manufacturer, ISO 13845 or equivalent

Declaration of Conformity (DoC) (Annex 6)

- A DoC is a declaration made by the manufacturer of a device that the device is in conformity with the regulatory requirements
- DoC declares that the manufacturer guarantees that each piece of the device sold is in conformity with the regulatory requirements

Summary Technical Documentation (Annex 4)

- format –ASEAN CSDT
- Compliance to EPSP *(GHTF recommendations - Essential Principles of Safety & Performance of Medical Devices)* (Art. 3)
- Acceptable standards or equivalence will be widely used (Art. 9)*(GHTF recommendations-Role of Standards in the Assessment of Medical Devices)*
- Authority / Notified Bodies determines the adequacy of the documented evidence to support attestation of conformity

Post-Market Surveillance System (PMS) (Annex 5)

- Distribution records
- Complaint records
- Adverse incident reporting *(GHTF recommendations - Medical Devices Post Market Surveillance: Global Guidance for Adverse Event Reporting for Medical Devices)*
- FSCA reporting *(GHTF recommendations - Medical Devices Post Market Surveillance: Content of Field Safety Notices)*

PROGRESS OF TRANSPOSITION

Transposition of AMDD	Y	N	Comments
Ratification of AMDD – Full Implementation	3	7	Singapore, Laos PDR and Vietnam
Ongoing Ratification	7	0	Brunei, Cambodia, Indonesia Malaysia. Myanmar. Phillipines, Thailand

Status:Ratification and Transposition of AMDD

Member States	Status
Brunei Darussalam	Ratification process expected to be completed by 2017
Cambodia	The AMDD is already translated into national language; The current registration guideline has been amended to be in line with the AMDD; Still in the process of ratification, expected to be ready by 2017.
Indonesia	Still in the domestic process for ratification; Based on the new trade law for international trade agreement has to go through the parliament; The document for ratification process already submitted to the parliament; The ratification of AMDD is targeted by 1st quarter of 2017;
Lao PDR	AMDD has been ratified on 25 May 2015; Original instrument of ratification has been submitted to the ASEAN Secretariat on 30 December 2015. Currently is preparing the guideline for the implementation of AMDD; Expected to have specific new law on medical device by 2020; Currently is revising the current law.

Ratification and Transposition of AMDD cont..

Member States	Status
Philippines	Awaiting approval for guidance document on implementation of AMDD, which is expected by end of 2016; Ratification of AMDD is expected to be submitted by 2016.
Singapore	Instrument of ratification has been submitted to the ASEAN Secretariat on 10 November 2015; Ready to fully implement AMDD.
Thailand	The Draft Amendment of Medical Device act was approved by the Cabinet. The internal procedures have to be done through the parliament for consideration and approval of this amendment. In the process of ratification, AMDD already submitted to the parliament for consideration and approval; Preparation for the implementation of AMDD is on-going including activities on capacity building for both regulators and industry; Ratification of AMDD is expected to be submitted 2017.

Member States	Status
Viet Nam	The Prime Minister of Vietnam signed Resolution No. 17/ NQ-CP dated 26/02/2016 approving AMDD and The Ministry of Foreign Affairs implemented the diplomatic procedures as prescribed The Government has established a Decree on management of medical devices and is expected to be issued in June 2016 which stipulates the contents according to AMDD about: definition, classification, registration setting system, quality control, technical documentation, publication conformity assessment and technical standard, labelling and post marketing alert system. Viet Nam has submitted the Instrument of Acceptance of AMDD to the ASEAN Secretariat on 21 March 2016.
Malaysia	The AMDD has been transposed into national legislation; In the midst of drafting the 2nd regulation which related to Article 22 of AMDD on Post Market Surveillance. The 2nd regulation will be gazetted end of 2016; Ratification of AMDD is expected by mid-2017.

Article 14-Institutional Structure

- Establishment of ASEAN Medical Device Committee (AMDC)
- Support from ACCSQ in assisting AMDC in implementing the AMDD
- AMDC at its liberty to establish ASEAN Medical Device Technical Committee (AMDTC), reviewing the technical and safety issues

Progress of MDPWG to AMDC

- Establishment of the ASEAN Medical Device Committee (AMDC)
- To coordinate,review and monitor the implementation of AMDD
- Comprise of representatives from Regulatory Authority of each Member State
- The ACCSQ and ASEAN Secretariat shall support in coordinating and monitoring the implementation of AMDD
- AMDC may establish ASEAN Medical Device Technical Committee (AMDTC) to assist the AMDC in reviewing the technical safety and safety issues.
- Milestone for completion of transposition process and submission of instrument of ratification by 2020. The milestone will include, among others, the following items

(i) Development of Guidelines for implementation of AMDD,

(ii) Implementation of AMDD in phases,

(iii) Monitoring of the implementation of AMDD

(iv) Development of a matrix on common interpretation of AMDD

Issues and Challenges related to implementation of AMDD

- Language of AMDD
- Transposition:The state of readiness of Member States to transpose the AMDD?
- Factors that can influence the speed of transposition
  - Capacity Building: Financial and Human Resource
  - Political situation and procedures within each economy
  - Current regulatory framework: Extensive or not
- PMS alert system

Issues and Challenges related to implementation to AMDD

- Rectification exercise
- Uneven economies although they are moving in the right direction
- Resources
- Expertise
- Common understanding among economies when implementing the directive
- Training

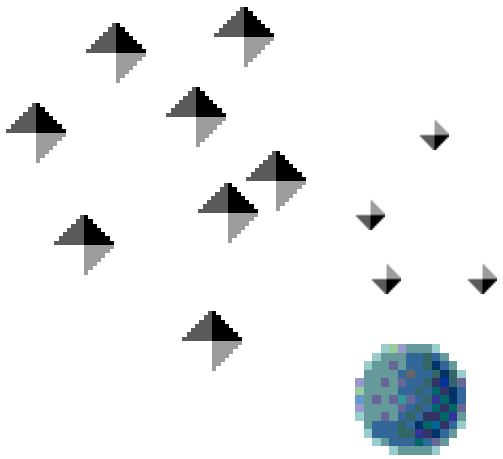
The reality of AMDD

- It defines submission of technical requirements to be harmonized
- It requires Member countries to register products and license establishments
- It states that development of the guidelines and standards that follows internationally recognized institutions and organisations

- Flexible in that Member states however, still retain their sovereign rights on how registration and licensing decisions
- It allows member countries to implement country specific measures of controls
- Focusing only on certain important aspect of medical device regulatory control and not aimed in harmonizing all of it

New Frontiers

- Combination Products
- Nanotechnology
- IVDs



Thank You